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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,773	03/22/2002	Arnold Hilgers	Q67842	1749

23373 7590 03/19/2003

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EXAMINER

NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 03/19/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,773

Applicant(s)

Hilgers

Examiner

Dave Nguyen

Art Unit

1632



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☒ Claim(s) 5-36 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Mar 22, 2002 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1 and 6 6) ☐ Other:

Claims 1-36 are pending for examination.

Claims 5-36 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim. See MPEP 608.01(n). Accordingly, the claim not been further treated on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 USC 102 (b) as being anticipated by any of Woiszvillo (US Pat No. 5,849,884), OctoPlus (EP 0 842 657), or Magnus (EP 0 213 303).

The composition as defined in the base claim 1 is partially defined as a produce-by-process. The claimed composition is claimed as a two-phase aqueous polymer system comprising i) a biological material, (ii) at least two compounds being incompatible in an aqueous solution, wherein the two compounds would lead to a spontaneous formation of a dispersed phase and iii) microparticles in the dispersed phase. The claimed composition or the two-phase aqueous polymer system is disclosed in numerous prior art of record. As an exemplified prior art, Woiszvillo teaches the same on column 3, line 21 –column 4, line 5, examples). OctoPlus teaches the same on pages 3-5. Particularly, OctoPlus teaches on page 4, lines 39-41, that suitable emulsifiers are copolymers, preferably block-copolymers, of units of the two incompatible polymers, e.g., a block-copolymer of PEG and Dextran, used to create the two-phase system. Magnus also teaches the same throughout the disclosure, particularly pages 2-4, 5-6, and 12. With respect to Woiszvillo: column 3 discloses that the polymers are carbohydrate based polymers, dextran or a polymer mixture of polyvinylpyrrolidone and polyethylene glycol (PEG); The MW of PEG is disclosed on column 12; Example 5, column 19 discloses that polylysine is employed as a nucleic acid binding agent; Column 10 discloses that surfactant composed of any

known phospholipid can be employed for attachment to the surface of the formed microparticles; and MW of Dextran is disclosed on column 22. With respect to Magnus, Magnus teaches that PEG and dextran can be used in a two-phase system, wherein MW of both are also disclosed, page 5; page 3 discloses that one way to achieve removal of water from the dispersed phase comprises the application of methods such as evaporation; Page 12 of Magnus also discloses that particles can be produced without heating, if the dispersed phase is dehydrated with a watermiscible solvent

The functional limitation of an occurrence of a spontaneous formation of the dispersed phase does not carry any patentable weight, since the office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same functional characteristics of the claimed product. In the absence of factual evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562, F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2d 1922, 1923 (BPAI 1989). Again, the claiming of a new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977); *In re Spada*, 15 USPQ2d 1655, Federal Circuit, 1990. See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

Furthermore, the skill of a person skilled in the art of making microparticles is relatively high, as evidenced by the totality of the prior art of record, and as such, it is well-recognized in the prior art that aqueous solutions of two incompatible polymers will spontaneously separate into a dispersed and continuous phase when a critical polymer concentration has been reached, e.g., evaporation of water. In fact, Woiszvillo teaches on column 12, last paragraph, that "the microparticles may be formed at lower temperatures by utilizing a higher macromolecule concentration". On the other hand, when two incompatible polymers are mixed in such a way that the concentration in the final mixture is already above the critical concentration (see column 7,

especially lines 32-40), mechanical energy (e.g., vortexing, stirring) should be put in the system in order to get a finely dispersed phase. Note also that although Woiszvillo teaches the use of conventional emulsification means, like stirring, vortexing and sonication, spontaneous formation of a dispersed phase is not excluded: the formation of microparticles can also be observed just by heating one-phase aqueous solutions of incompatible polymers, e.g., example 14.

Thus, the claims are anticipated by the cited references.

Note also that it is well recognized by a person of ordinary skill in the art, as evidenced by the totality of the prior art of record, that a dispersed phase would form when a critical polymer concentration has been reached, and that it is within the purview of those of ordinary skill in the art of making microparticles to employ any concentration step such as evaporation without heating in order to achieve the critical polymer concentration required for the formation of a dispersed phase in a two-phase system comprising to incompatible polymers such as dextran and PEG, and a biologically active material such as a nucleic acid molecule.

The following references are cited to further show that it is well recognized by a person of ordinary skill in the art that a dispersed phase would form when a critical polymer concentration has been reached, and that it is within the purview of those of ordinary skill in the art of making microparticles to employ any concentration step such as evaporation without heating in order to achieve the critical polymer concentration required for the formation of a dispersed phase in a two-phase system comprising to incompatible polymers such as dextran and PEG: Orly, US Pat No. 5,672,301, Gibson, US 6,291,013, Hennink, US 6,303,148 and US 6,395,302.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

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Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
Art Unit: 1632

A handwritten signature in black ink, appearing to be 'D' followed by a long horizontal stroke.

DAVE T. NGUYEN
PRIMARY EXAMINER